# Reports to the Drug Enforcement Administration

21 U.S.C. § 830 and 21 CFR Part 1310

## Types of Required Reports

In addition to periodic written reports required of bulk manufacturers and certain mail order distributors, there are four events that require prompt oral reporting to DEA.

## Oral Reports

21 CFR § 1310.05

There are four types of transactions specified in the CSA which require a regulated person to make oral notification to the Special Agent in Charge, or a designee, of the local DEA Division Office whenever possible. The oral report must be made as soon as possible, and as far in advance of the conclusion of the regulated transaction, as possible. A written report of a transaction listed in paragraphs 1, 3, and 4 below is required to be sent to that office within 15 days after the regulated person becomes aware of the circumstances of the event. The four circumstances are:

1. Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law.

2. Any proposed regulated transaction with a person whose description or other identifying characteristic has been previously furnished by DEA to the regulated person. Such a transaction may not be completed unless the transaction is approved by DEA.

3. Any unusual or excessive loss or disappearance of a listed chemical that is under the control of the regulated person. The regulated person responsible for reporting a loss in transit is the supplier.

4. Any regulated transaction involving a tableting or encapsulating machine.

## Recognizing Suspicious Orders

21 U.S.C. § 830 (b) (1) (A)

The law, 21 U.S.C. § 830 (b)(1)(A), requires that each regulated person shall report to the Attorney General any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. While reporting suspicious orders to DEA is required by law, the manner in which industry addresses the requirement determines its effectiveness.

In 1998 representatives of the chemical industry, including those whose products contain pseudoephedrine, phenylpropanolamine and other chemicals sought by drug traffickers, met in the Suspicious Orders Task Force with representatives of federal, state and local law enforcement and prosecutors. The Suspicious Orders Task Force considered issues relating to the diversion of these products. Industry representatives helped develop guidelines and expressed a willingness to distribute them through industry publications. They also agreed to incorporate the guidelines into existing employee training programs. One set of guidelines is the "Suspicious Orders Identification Criteria" for recognizing potential diversion at all levels of the distribution chain. Another set of guidelines is for use in automated tracking systems. See Appendix E for suspicious order identification criteria.

When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making the required reports, the transaction should not be completed until the customer is able to eliminate the suspicions. The distributor may have to forego some transactions. When DEA reviews distributor decisions, minor events are not cause for government action. At the same time a regulated person who fails to implement a system to prevent diversion will be closely scrutinized and if warranted, may be subject to civil, administrative, or criminal penalties.

The Task Force concluded that the term "suspicious order" had different meanings at different levels of the manufacturing and distribution chain. Accordingly, the recommendations of the Task Force and the definition of "suspicious" are specific for each group: Importers & Manufacturers; Wholesale Distributors; and Retail Distributors. Task Force findings appear in the appendices.

## Bulk Manufacturers' Reports

Regulated bulk manufacturers of listed chemicals are required to submit manufacturing, inventory, and use data on an annual basis to DEA, Drug and Chemical Evaluation Section, Washington, D.C. 20537. Reports are due by March 15 of the year immediately following the calendar year in which the inventory took place. Details of reporting requirements appear in 21 CFR §1310.05(d) and §1310.06(h).

# Reports of Mail Order Distributions

21 U.S.C. § 830 (b) (3) (A)

Each regulated person who engages in a transaction with a non-regulated party (a consumer or end-user who does not re-distribute) which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals) via postal service, private carrier or commercial carrier, is required to submit a monthly report of all such transactions regardless of the size of the transaction.

The reports must include the name of the purchaser; the quantity and form of the ephedrine, pseudoephedrine, or phenylpropanolamine purchased; the date of each transaction; the address to which the product was sent; and such other items of information which DEA may by regulation require. Reports should be sent to the Chemical Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537. Regulated persons should check with DEA for the latest requirements.

The following distributions of drug products to non-regulated persons are exempted from the mail order reporting requirements:

1. Distributions of sample packages of drug products when those packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.
2. Distributions by retail distributors that may not include face-to-face transactions, to the extent that such distributions are consistent with the activities of a retail distributor.
3. Distributions to a resident of a long term care facility, or to a long term care facility for dispensing to or use by a resident of that facility.
4. Distributions in accordance with a valid prescription.
5. Exports which have been reported to DEA under the transshipment reporting requirements (21 CFR 1313.31), or the international transaction reporting requirements (21 CFR 1313.32), or for which advance notification reporting requirements are waived (21 CFR 1313.21).

DEA may revoke exemptions for regulated persons whose distributions are found to violate the regulations.

# Imports, Exports, and International Transactions

## Import/Export Declaration - DEA Form 486

21 U.S.C. § 971 and 21 CFR § 1313.12, 21, 32, 34

An Import/Export Declaration, DEA Form 486, must be completed by each regulated person for each regulated import, export, or international transaction. For the first shipment to a new customer, this form must be received by DEA at least 15 days prior to the import, export, or international transaction of the listed chemical. The exceptions to the 15-day rule are explained in the following paragraphs. Failure to complete the DEA Form 486 entirely and accurately may result in the shipment being suspended.

## General Waiver of Advance Notification Requirement

21 U.S.C. § 971 (e) (2), (3) and 21 CFR § 1313.12 (c) (2), (e), (f) and § 1313.21 (c) (2), (e), (f)

DEA may determine in some circumstances that effective diversion control does not require advance notification for a regulated import of a listed chemical or a regulated export to a specific country. In those circumstances, DEA may issue a regulation waiving the notification requirement and no Form 486 is required. The regulated person, however, must submit summary quarterly reports. The requirement has been waived for imports of acetone, 2-butanone, and toluene.

## Waiver of 15-day Advance Notification Requirement for Regular Customers or Regular Importers

21 CFR § 1313.15, 24

The 15-day advance notification requirement for regulated imports and exports of a listed chemical by regular customers or suppliers may be waived in the circumstances listed below. It is important to note that although the 15-day advance notification may be waived, the DEA Form 486 must be received by DEA, Chemical Control Section, on or before the date of importation or exportation. Form 486 should be mailed to: Drug Enforcement Administration, Chemical Control Section, P.O. Box 28346, Washington, D.C. 20038, or transmitted by facsimile to (202) 307-4702.

# Criteria for Waiver of Advance Notification Requirement

**For importers**, the 15-day advance notification requirement may be waived for any regulated person with an established record as an importer. To have an established record as an importer, the regulated person must have imported a listed chemical[1] at least once within the past six months, or twice within the past 12 months from a foreign supplier. The term also means that the regulated person has provided DEA with the following information:

1. the name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and
2. the frequency and number of transactions occurring during the preceding 12-month period.

**For exporters**, the 15-day advance notification requirement may be waived for any regulated person who has an established business relationship with a foreign customer. An established business relationship with a foreign customer means that the regulated person has exported a listed chemical[2] at least once within the past six months, or twice within the past 12 months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. The term also means that the regulated person has provided DEA with the following information:

1. the name and street address of the chemical exporter and of each regular customer,
2. the telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer,
3. the nature of the regular customer's business (i.e. importer, exporter, distributor, manufacturer, etc.) and if known, the use to which the listed chemical or chemicals will be applied,
4. the duration of the business relationship,
5. the frequency and number of transactions occurring during the preceding 12-month period,
6. the amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and the regular customer,
7. the method of delivery, and
8. other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

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1 A regular importer of any of these chemicals - acetone, methyl ethyl ketone, or toluene - is qualified as a regular importer of all three chemicals, unless DEA notifies an importer to the contrary.

2 A regular customer of any one of these three chemicals - acetone, methyl ethyl ketone, or toluene - is qualified as a regular customer of all three chemicals, unless DEA notifies an exporter to the contrary.

## Disqualification of Waiver

21 U.S.C. § 971 (c) and 21 CFR § 1313.15 (c), § 1313.24 (e)

If there are grounds to believe that the chemical being imported or exported may be diverted to the clandestine manufacture of a controlled substance, DEA may disqualify the importer or exporter from the "regular customer" or "regular importer" status and thereby terminate the waiver of the advance notification requirement. A written notice explaining the reasons for such disqualification will be provided. The regulated person is entitled to a hearing within 45 days after written request.

## Exports in Violation of Foreign Laws

21 CFR § 1313.25

It is incumbent upon the exporter, broker or trader to assure that each chemical export from the United States complies with the laws and regulations of the destination country. Exporters may contact DEA Office of Diversion Control, Chemical Control Section, for information on a specific country. If a shipment is found to be in violation of the laws of the foreign country, the exporter is subject to a penalty of up to 10 years imprisonment under 21 U.S.C. 960(d), and 18 U.S.C. 3571(3) provides for a $250,000 fine for an individual, and a $500,000 fine for an organization for each violation.

## Execution of the Import/Export Declaration – DEA Form 486

21 CFR § 1313.12-14, 21-23, 32

The Import/Export Declaration, DEA Form 486, is a three-part form that may be acquired from the nearest DEA office or may be downloaded for printing from the diversion control website, www.DEAdiversion.usdoj.gov>On-Line Forms and Applications.

A DEA Form 486 must be completed by each regulated person for each regulated import, export, or international transaction. Form 486 is distributed as follows:

1. Copy 1 is to be retained by the importer, exporter, or broker/trader as an official record of the import, export, or international transaction;
2. Copy 2 serves as the notification copy. To assure that the completed copy 2 of the DEA Form 486 is received as soon as possible by DEA, it should be mailed to: Drug Enforcement Administration, P.O. Box 27284, Chemical Control Section, Washington, D.C. 20038.
3. Copy 3 is presented to the U.S. Customs Service:
    a. For **imports**, with the customs entry form.
    b. For **exports**, at the port of exit along with the Department of Commerce Shipper's Export Declaration for each export of a listed chemical.
    c. For **international transactions involving a broker or trader**, copy 3 is retained by the broker or trader as the official record of the international transaction. Declaration forms must be retained for two years.

If the 15-day advance notice has been waived for an import or export, it must be so indicated on the DEA Form 486 by checking the appropriate block (1c.) If a waiver has been granted, the DEA Form 486 must be received in Headquarters on or before the date of the import or export.

If a waiver has not been granted, the DEA Form 486 must be received by DEA at least 15 days prior to the date of import, export, or other international transaction.

The completed copy may be sent to DEA via electronic facsimile if desired. The DEA import/export facsimile number is (202) 307-4702.

## Transshipment through the United States

21 CFR § 1313.31

A chemical imported for transshipment or transit through the United States for immediate exportation is subject to notification requirements if the quantity equals or exceeds the threshold amount. DEA must be notified at least 15 days prior to the proposed transshipment date. The notification must be in the form of a notice or letter (not a DEA Form 486) providing pertinent details of the transshipment and must be received by DEA at least 15 days prior to the proposed transshipment date. The notification either may be mailed to the Drug Enforcement Administration, PO Box 27284, Washington, D.C. 20038, or may be sent via electronic facsimile to (202) 307-4702. The following details must be included:

1. The date the notice was executed;
2. The complete name and description of the listed chemical as it appears on the label or container;
3. The name of the chemical as it appears in 21 CFR §1310.02 and as listed in this manual;
4. The number of containers and the size or weight of each container for each listed chemical;
5. The net weight of each listed chemical given in kilograms;
6. The gross weight of the shipment given in kilograms;
7. The name, address, telephone number, business of foreign exporter, telex number, and, where available, the facsimile number;
8. The foreign port of exportation;
9. The approximate date of exportation;
10. The complete identification of the exporting carrier;
11. The name, address, business, telephone number, telex number, and, where available, the facsimile number of the importer, transferor, or transshipper;
12. The U.S. port of entry;
13. The approximate date of entry;
14. The name, address, telephone number, telex number, business of the consignee and, where available, the facsimile number of the consignee at the foreign port of entry;
15. The shipping route from the U.S. port of exportation to foreign port of entry at final destination;
16. The approximate date of receipt by the consignee at the foreign port of entry; and
17. The signature of the importer, transferor, transshipper, or agent, accompanied by the agent's title.

## Returned Export

21 CFR § 1313.22 (e)

When an export of a listed chemical is refused, rejected or otherwise deemed undeliverable, it may be returned to the U.S. chemical exporter of record. A brief written notification (not a DEA Form 486) must be sent to DEA within a reasonable period of time outlining the circumstances. This explanation must be sent to the following address: Drug Enforcement Administration, Chemical Control Section, P.O. Box 27284, Washington, D.C. 20038. This does not apply to a shipment that has cleared foreign customs, been delivered and accepted by the foreign consignee. The application of this provision requires that rejection of the chemical by the consignee occur within reasonable proximity to the delivery (i.e., the "acceptance" of the chemical would be indicated by such events as full payment for the chemical and its introduction into inventory). A return to a third party in the United States will be regarded as an import.

## Special Policy Regarding Exports of Certain Chemicals to Colombia

In March, 1996, the United States Government (U.S.G.) took steps to decertify Colombia's status as a nation actively cooperating with the United States on drug control. DEA has historically experienced great difficulty in determining the legitimacy and final destination of exports of chemicals from the United States to Colombian companies. Additionally, DEA is unable to rely on the Colombian government to insure that listed chemicals imported from the United States and other sources are not diverted to illicit drug manufacture. Following the U.S.G.'s decertification, DEA revoked regular customer status for all U.S. exports of the following cocaine essential chemicals to Colombia: acetone, potassium permanganate, MEK, MIBK, toluene, and ethyl ether. Despite the fact that since then Colombia has become conditionally certified, DEA continues to employ a heightened standard of review to scrutinize proposed exports and transshipments to Colombia because of the high probability that these chemicals may be diverted to the clandestine manufacture of cocaine. Details can be found in the Federal Register Notice dated March 28, 1996, pages 13759-13760 which establishes and explains this policy (Appendix F).

## Suspension of Shipments

21 U.S.C. § 971 (c) and 21 CFR § 1313.41

The Administrator may suspend any importation or exportation of a listed chemical based on evidence that the chemical may be diverted to the clandestine manufacture of a controlled substance. DEA will provide written notice to the regulated person explaining the legal and factual basis of the suspension. The regulated person may request an administrative hearing to determine the issues involving the suspension. A request for a hearing must be made within 30 days after receipt of the suspension notice.

## Confidentiality

DEA collects confidential business information (CBI) from required reports and may collect CBI in the course of investigations. With respect to the chemical program, the release of CBI that is protected from disclosure under Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4) is governed by Section 830(c) of the CSA (21 U.S.C. § 830 (c)) and the Department of Justice procedures set forth in 28 CFR §16.7. The CSA (21 U.S.C. § 830) provides that information that is protected from disclosure under Exemption 4 may only be released in circumstances related to the enforcement of controlled substance or chemical laws, customs laws, or for compliance with U.S. obligations under treaty or international agreements. The Department of Justice procedures establish that if a FOIA request is received for release of information that is protected under Exemption 4, the submitter of the protected information must be notified of such a request, given an opportunity to object to the disclosure, and allowed to provide justification as to why the information should not be disclosed.

In addition to the statutory and regulatory requirements, DEA has established internal guidelines governing the handling of CBI, including provisions that the material be maintained in locked containers, that access to the information be on a need-to-know basis, and that any disclosure under Section 830 be made only pursuant to a non-disclosure agreement by the receiving party.

**Appendix A**

# Identification Codes for Listed Chemicals – List I Chemicals

The following section presents the DEA Code, the Harmonized Code, and the Chemical Abstract Number for List I and List II chemicals. Note that individual salts, isomers, esters, salts of esters, and salts of isomers have unique Chemical Abstract Numbers.

| List I Chemicals | | | |
|---|---|---|---|
| **Chemical** | **DEA Code** | **New Harmonized Code** | **Chemical Abstract Number** |
| N-Acetylanthranilic acid *and its salts and esters* | 8522 | 2924.29.7590 | [89-52-1] |
| Anthranilic acid *and its salts and esters* | 8530 | 2922.43.0000 | [118-92-3] |
| Benzaldehyde | 8256 | 2912.21.0000 | [100-52-7] |
| Benzyl cyanide | 8735 | 2926.90.4700 | [140-29-4] |
| Ephedrine *and its salts, optical isomers, and salts of optical isomers* | 8113 | 2939.41.0000 | [299-42-3] |
| Ergonovine *and its salts (Tariff name:Ergometrine)* | 8675 | 2939.61.0000 | [60-79-7] |
| Ergotamine *and its salts* | 8676 | 2939.62.0000 | [113-15-5] |
| Ethylamine *and its salts* | 8678 | 2921.19.1000 | [75-04-7] |
| Gamma-butyrolactone | 2011 | 2932.29.5010 | [96-48-0] |
| Hydriodic acid (57%) | 6695 | 2811.19.6050 | [10034-85-2] |
| Isosafrole | 8704 | 2932.91.0000 | [120-58-1] |
| Methylamine *and its salts* | 8520 | 2921.11.0000 | [74-89-5] |
| 3, 4-Methylenedioxyphenyl-2-propanone *(Tariff name: 1-(1,3-benzodioxol-5-yl)-2-propanone)* | 8502 | 2932.92.0000 | 4676-39-5] |
| N-Methylephedrine *and its salts, optical isomers, and salts of optical isomers* | 8115 | 2939.49.0000 | [552-79-4] |
| N-Methylpseudoephedrine *and its salts, optical isomers, and salts of optical isomers* | 8119 | 2939.49.0000 | [14222-20-9] |
| Nitroethane | 6724 | 2904.90.0000 | [79-24-3] |
| Norpseudoephedrine *and its salts, optical isomers, and salts of optical isomers* | 8317 | 2939.49.0000 | [492-39-7] |
| Phenylacetic acid *and its salts and esters* | 8791 | 2916.34.1000 | [103-82-2] |
| Phenylpropanolamine *and its salts, optical isomers, and salts of optical isomers* | 1225 | 2939.49.0000 | [14838-15-4] |
| Piperidine *and its salts* | 2704 | 2933.32.1000 | [110-89-4] |
| Piperonal | 8750 | 2932.93.0000 | [120-57-0] |
| Propionic anhydride | 8328 | 2915.50.5000 | [123-62-6] |
| Pseudoephedrine *and its salts, optical isomers, and salts of optical isomers* | 8112 | 2939.42.0000 | [90-82-4] |
| Safrole (*includes safrole-rich essential oils, such as sassafras oil and camphor oil 1070)* | 8323 | 2932.94.0000 | [94-59-7] |
| Red Phosphorus | 6795 | 2804.70.0000 | [7723-14-0] |
| White Phosphorus | 6796 | 2804.70.0000 | [7723-14-0] |
| Hypophosphorus acid *and its salts* | 6797 | 2811.19.6050 | [6303-21-5] |

## Appendix A

# Identification Codes for Listed Chemicals – List II Chemicals

The following section presents the DEA Code, the Harmonized Code, and the Chemical Abstract Number for List II chemicals. Note that individual salts, isomers, esters, salts of esters, and salts of isomers have unique Chemical Abstract Numbers.

| List II Chemicals | | | |
|---|---|---|---|
| **Chemical** | **DEA Code** | **New Harmonized Code** | **Chemical Abstract Number** |
| Acetic anhydride | 8519 | 2915.24.0000 | [108-24-7] |
| Acetone | 6532 | 2914.11.1000/ 2914.11.5000 | [67-64-1] |
| Benzyl chloride | 8570 | 2903.69.2000 | [100-44-7] |
| Ethyl ether | 6584 | 2909.11.0000 | [60-29-7] |
| Hydrogen chloride | 6545 | 2806.10.0000 | [7647-01-0] |
| Iodine | 6699 | 2801.20.0000 | [7553-56-2] |
| Methyl ethyl ketone (2-Butanone) | 6714 | 2914.12.0000 | [78-93-3] |
| Methyl isobutyl ketone (MIBK) | 6715 | 2914.13.0000 | [108-10-1] |
| Potassium permanganate | 6579 | 2841.61.0000 | [7722-64-7] |
| Sulfuric acid | 6552 | 2807.00.0000 | [7664-93-9] |
| Toluene | 6594 | 2902.30.0000 | [108-88-3] |

## Appendix B

# Thresholds for Regulated Transactions in List I Chemicals

Excluded transactions are listed following the table "Thresholds for Regulated Transactions in List II Chemicals"

| List I Chemical | Threshold by base weight |
|---|---|
| N-Acetylanthranilic acid *and its salts and esters* | 40 kilograms |
| Anthranilic acid *and its salts and esters* | 30 kilograms |
| Benzaldehyde | 4 kilograms |
| Benzyl cyanide | 1 kilogram |
| Ephedrine *and its salts, optical isomers, and salts of optical isomers* | 0 kilograms |
| Ergonovine *and its salts* | 10 grams |
| Ergotamine *and its salts* | 20 grams |
| Ethylamine *and its salts* | 1 kilogram |
| Gamma-butyrolactone | 0 kilograms[1] |
| Hydriodic acid (57%) | 1.7 kilograms (or 1 liter by volume) |
| Hypophosphorous acid *and its salts* | 0 kilograms[1] |
| Isosafrole | 4 kilograms |
| Methylamine *and its salts* | 1 kilogram |
| 3,4-Methyenedioxyphenyl-2-propanone | 4 kilograms |
| N-Methylephedrine *and its salts, optical isomers, and salts of optical isomers* | 1 kilogram |
| N-Methylpseudoephedrine *and its salts, optical isomers, and salts of optical isomers* | 1 kilogram |
| Nitroethane | 2.5 kilograms |
| Norpseudoephedrine *and its salts, optical isomers, and salts of optical isomers* | 2.5 kilograms |
| Phenylacetic acid *and its salts and esters* | 1 kilogram |
| Phenylpropanolamine *and its salts, optical isomers, and salts of optical isomers* | 2.5 kilograms |
| Phosphorus, red, white | 0 kilograms[1] |
| Piperidine *and its salts* | 500 grams |
| Piperonal | 4 kilograms |
| Propionic anhydride | 1 gram |
| Pseudoephedrine *and its salts, optical isomers, and salts of optical isomers* | 1 kilogram |
| Safrole *includes safrole-rich essential oils, such as sassafras oil and camphor oil 1070* | 4 kilograms |

1 See Appendix B-1 for excluded transactions

**Appendix B**

# Thresholds for List I Chemicals in Drug Products

| | Threshold by Base Weight | | | |
|---|---|---|---|---|
| **List I chemicals in Drug Products** | **Distributions by retail distributors** | **Distributions by mail order reporters** | **All other domestic distributions** | **Imports and exports** |
| **Ephedrine**[1] | | | | |
| As the sole therapeutically significant ingredient | No threshold – all transactions regulated | No threshold – all transactions regulated | No threshold – all transactions regulated | No threshold – all transactions regulated |
| In combination with therapeutically significant amounts of another medicinal ingredient | 24 grams[2] | 24 grams[2] | 1 kilogram | 1 kilogram |
| **Pseudoephedrine**[1] | | | | |
| Other than ordinary over-the-counter products | 9 grams[2,3] | 9 grams[2,3] | 1 kilogram | 1 kilogram |
| Ordinary over-the-counter products | Exempt | 9 grams[2,3] | 1 kilogram | 1 kilogram |
| **Phenylpropanolamine**[1] | | | | |
| Other than ordinary over-the-counter products | 9 grams[2,3] | 9 grams[2,3] | 2.5 kilograms | 2.5 kilograms |
| Ordinary over-the-counter products | Exempt | 9 grams[2,3] | 2.5 kilograms | 2.5 kilograms |

1 And its salts, optical isomers, and salts of optical isomers
2 Per single transaction
3 Limited to packages of not more than three grams of base per package

**Appendix B**

# Thresholds for Regulated Transactions in List II Chemicals

| List II Chemicals | Domestic Sales | | Imports and Exports | |
|---|---|---|---|---|
| | By volume | By weight | By volume | By weight |
| Acetic anhydride | 250 gallons | 1023 kgs | 250 gallons | 1023 kgs |
| Acetone | 50 gallons[1] | 150 kgs[1] | 500 gallons[2] | 1500 kgs[2] |
| Benzyl chloride | Not applicable | 1 kg | Not applicable | 4 kgs |
| Ethyl ether | 50 gallons | 135.8 kgs | 500 gallons | 1364 kgs |
| Hydrochloric acid[2] | Not regulated | Not regulated | 50 gallons[3] | Not applicable |
| Anhydrous hydrogen chloride[2] | Not applicable | 0.0 kgs[4] | Not applicable | 27 kgs[3] |
| Iodine | Not applicable | 0.4 kgs | Not regulated | Not regulated |
| Potassium permanganate | Not applicable | 55 kgs | Not applicable | 500 kgs |
| Methyl ethyl ketone (2-Butanone) | 50 gallons[1] | 145 kgs[1] | 500 gallons[2] | 1455 kgs[2] |
| Methyl isobutyl ketone (MIBK) | Not regulated | Not regulated | 500 gallons[3] | 1523 kgs[3] |
| Sulfuric acid | Not regulated | Not regulated | 50 gallons[3] | Not applicable |
| Toluene | 50 gallons[1] | 159 kgs[1] | 500 gallons[2] | 1591 kgs[2] |

1 The cumulative threshold is not applicable to domestic sales of acetone, methyl ethyl ketone, and toluene.
2 The 15 day advance notification requirement for imports is waived. Importers must provide quarterly reports as indicated in 21 CFR 1313.12(e).
3 Threshold applies to exports, transshipments, and international transactions to western hemisphere except Canada. Imports are not regulated.
4 See Appendix B-1 for excluded transactions.

**Appendix B**

# Table of Concentration Limits for Mixtures Containing Ephedrine, N-Methylephedrine, N-Methylpseudoephedrine, Norpseudoephedrine, Phenylpropanolamine, or Pseudoephedrine

| List I chemicals | DEA chemical code | Concentration (percent) | Special conditions |
|---|---|---|---|
| Ephedrine, *its salts, optical isomers, and salts of optical isomers.* | 8113 | 5% by Weight, (weight includes capsule, if any). | Concentration based on any combination of ephedrine, pseudoephedrine, and their salts, optical isomers and salts of optical isomers |
| N-Methylephedrine, *its salts, optical isomers, and salts of optical isomers.* | 8115 | 0.1% by Weight, (weight includes capsule, if any). | Concentration based on any combination of N-methylephedrine, N-methylpseudoephedrine and their salts, optical isomers and salts of optical isomers |
| N-methylpseudoephedrine, *its salts, optical isomers, and salts of optical isomers.* | 8119 | 0.1% by Weight (weight includes capsule, if any). | Concentration based on any combination of N-methylpseudoephedrine, N-methylephedrine, and their salts, optical isomers and salts of optical isomers |
| Norpseudoephedrine, *its salts, optical isomers, and salts of optical isomers.* | 8317 | 0.6% by Weight (weight includes capsule, if any). | Concentration based on any combination of norpseudoephedrine, phenylpropanolamine and their salts optical isomers and salts of optical isomers |
| Phenylpropanolamine, *its salts, optical isomers, and salts of optical isomers.* | 1225 | 0.6% by Weight (weight includes capsule, if any). | Concentration based on any combination of phenylpropanolamine, norpseudoephedrine and their salts, optical isomers and salts of optical isomers |
| Pseudoephedrine, *its salts, optical isomers, and salts of optical isomers.* | 8112 | 5% by Weight, (weight includes capsule, if any). | Concentration based on any combination of pseudoephedrine, ephedrine, and their salts, optical isomers and salts of optical isomers |

**Appendix B-1**

# Excluded Transactions 21CFR 1310.08

The following transactions have been determined by DEA to be excluded from the definition of regulated transaction.

Anhydrous hydrogen chloride

- exports, transshipments, and international transactions except for exports, transshipments, and international transactions to:
  Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Panama,
  Paraguay, Peru, Suriname, Uruguay, Venezuela
- import transactions
- domestic distribution weighing 12,000 pounds net weight or more in a single container
- domestic distribution by pipeline

Gamma-butyrolactone

- domestic, import, and export distributions of gamma-butyrolactone weighing 4,000 kilograms (net weight) or more in a single container

Hydrochloric acid and sulfuric acid (but not anhydrous hydrogen chloride):

- domestic and import transactions
- exports, transshipments, and international transactions except for exports, transshipments, and international transactions to:
  Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Panama,
  Paraguay, Peru, Suriname, Uruguay, Venezuela

Iodine

- import and export transactions

Methyl isobutyl ketone (MIBK):

- Domestic transactions
- Import transactions destined for the United States
- Export transactions, international transactions, and import transactions for transshipment or transfer of methyl isobutyl ketone destined for Canada or any country outside of the Western Hemisphere

Red or white phosphorus

- domestic and international return shipments of reusable containers from customer to producer containing residual quantities of red phosphorus or white phosphorus in rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2500 gallons in a single container)

## Appendix C
# Dosage Unit Conversion Tables for Drug Product Thresholds1

| Combination Ephedrine Threshold | | |
|---|---|---|
| **Tablet Type and Strength** | **Number of Tablets** | |
| | **Wholesale: 1000 grams** | **Retail: 24 grams** |
| 25mg Tablets HCl | 48,827 | 1,172 |
| 25mg Tablets Sulfate | 51,872 | 1,245 |

| Pseudoephedrine Threshold | | | |
|---|---|---|---|
| **Tablet Type and Strength** | **Number of Tablets** | | |
| | **Wholesale: 1000 grams** | **Retail: 9 grams** | **3 gram package limit** |
| 120mg Tablets HCl | 10,173 | 92 | 31 |
| 120mg Tablets Sulfate | 10,806 | 98 | 33 |
| 60mg Tablets HCl | 20,345 | 184 | 62 |
| 60mg Tablets Sulfate | 21,614 | 195 | 65 |
| 30mg Tablets HCl | 40,689 | 367 | 123 |
| 30mg Tablets Sulfate | 43,227 | 390 | 130 |

| Phenylpropanolamine Threshold[2] | | | |
|---|---|---|---|
| **Tablet Type and Strength** | **Number of Tablets** | | |
| | **Wholesale: 1000 grams** | **Retail: 9 grams** | **3 gram package limit** |
| 75mg Tabs HCl | 41,371 | 149 | 50 |
| 25mg Tabs HCl | 124,113 | 447 | 149 |
| 12.5mg Tabs HCl | 248,224 | 894 | 298 |
| 6.25mg Tabs HCl | 496,452 | 1,788 | 596 |

1 Retail transactions of ordinary over-the-counter products in face-to-face transactions to individuals for personal use and in quantities below these thresholds are not regulated transactions. The 9-gram threshold on retail sales does not apply to ordinary over-the-counter non-liquid products sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base, and packaged in blister packs, each blister containing not more than two dosage units, or where the use of blister packs is technically infeasible, packaged in unit dose packets or pouches; and for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or phenylpropanolamine base. Distributors who engage in non-retail transactions must comply with the registration, record keeping, reporting, proof of identity and security requirements of the law.

2 Due to concerns regarding harmful side effects of phenylpropanolamine, the Food and Drug Administration has invoked a voluntary ban on over-the-counter phenylpropanolamine products.

## Appendix D

# Voluntary Cooperation

**The legitimate industry has taken the opportunity to join the drive against drug abuse. Industry's voluntary initiatives demonstrate the importance that it places on keeping its products out of the hands of drug traffickers. Following are some ways in which the chemical industry has been able to assist in preventing diversion of chemicals into the illicit drug traffic.**

### Notifying in Advance of the 15-Day Export Requirement

The CSA requires that each regulated person who exports a listed chemical which meets or exceeds the threshold limits must notify DEA of the exportation not later than 15 days before the export is to take place. This 15-day period provides DEA the opportunity to verify the legitimacy of the consignee and to take necessary action to stop the shipment if it is determined that it may be diverted into the illicit traffic. Such verification must be coordinated with one or more foreign DEA offices and with the host country authorities, and it is, by nature, time-consuming. DEA's efforts can be greatly enhanced if industry notifies DEA of an export of a listed chemical as much in advance as possible.

### Reporting of Changes in Amount Imported

The regulations require quarterly summary reporting by importers whose imports were made under waiver of advanced notification. (This is in addition to the filing of Form 486.) Voluntary reports in situations involving all List I chemical imports would be of great use in accurately capturing this critical import data, which does not now capture reductions to initially declared data.

### Educating Subsidiary Companies

Frequently, a U.S. chemical supplier exports a listed chemical to a subsidiary company for further distribution. It is important that a U.S. chemical firm educate its subsidiaries with regard to the severity of the chemical diversion problem and encourage them to implement voluntary controls to prevent diversion and subsequent clandestine use of the chemical.

### Examples of Voluntary Initiatives that Companies Have Taken

Several companies have implemented voluntary programs which go beyond the minimum required by law, to ensure that their products or operations do not become a part of the methamphetamine problem.

Following are examples of the voluntary programs undertaken by retail distributors and manufacturers/wholesale distributors.

### Retail Distributors

**1) Sale Quantity Limits:** Several retailers established voluntary sales limits which are substantially lower than 9 grams, and include "blister pack" sales, although these are exempt from mandatory retail controls. These firms have concluded that the vast majority of their legitimate consumer sales are unaffected by these voluntary limits, and at the same time the limits ensure that their stores do not unwittingly become a source of supply for the illicit manufacture of methamphetamine.

**2) Point of Sale Messages at Cash Registers:** Separately or in conjunction with "sale quantity limits" programs implemented above, several companies whose stores have an electronic, or "point-of-sale" check out system, have programmed an operator message to appear on the cashier's register. This message indicates when a customer attempts to purchase more than the store's established limits for these over-the-counter (OTC) medications. In most cases, no other merchandise may be scanned until the cashier overrides the message.

**3) Sign Postings:** Several retailers posted signs on the shelves containing cold, flu, allergy, and asthma medications, as well as at the check out registers to notify their customers about their policy restricting the sale of products containing ephedrine, pseudoephedrine, or phenylpropanolamine. These signs have ranged from the company announcing that they are working in cooperation with DEA to a simple notification of the sale quantity limit.

**4) Limiting Shelf Stock:** Several companies are limiting the shelf space given to OTC products which contain pseudoephedrine or phenylpropanolamine, thus requiring any customer seeking an excessive amount of these products to make inquiries with store personnel. Some chain warehouses are also limiting the amount of stock any retail store may order, thus limiting the possibility of diversion. These actions will help prevent the loss of significant amounts of a store's stock of these products through theft.

**5) Education of Employees:** Several companies do not have electronic, or point-of-sale, check-out systems at their cash registers. However, they have established a program to inform employees of the company's policy concerning the restriction of OTC products containing ephedrine, pseudoephedrine or phenylpropanolamine and the names of products whose sales are limited.

**6) Placing Selected Products behind the Counter:** The monitoring of sales trends over time can identify unusual increases, indicating that perhaps products are being diverted to clandestine methamphetamine laboratories.

**7) Notifying Law Enforcement:** The participation of legitimate industry is an essential element in the fight against methamphetamine abuse, through such voluntary programs as those previously cited. Law enforcement relies on information provided by concerned citizens in order to effectively fight chemical diversion. The limiting of the number of OTC products that may be purchased at one time is an essential step. However, laboratory operators will seek out other sources, especially those who may not be implementing such programs. Notifying local law enforcement of attempted excess purchases has proven useful.

**Manufacturer/Wholesale Distributor Initiatives**

**1) Limitation of Product Line:** Manufacturers and wholesale distributors have aggressively enhanced their role in preventing the diversion of these OTC products for the illicit manufacture of methamphetamine:

- The Methamphetamine Anti-Proliferation Act of 2000 placed controls on retailers engaging in "non-blister pack" single transaction sales of over 9 grams for products containing pseudoephedrine or phenylpropanolamine.

- Several manufacturers and custom label wholesale distributors discontinued their packages containing 60 or more count bottles of these OTC products, which are the sizes most

preferred by traffickers. Small quantity "blister packs" increase the difficulty for clandestine laboratory operators using these tablets.

**2) Education of Employees:** Several manufacturers and wholesale distributors are also aware that the best offense is a good defense. These firms have developed educational programs for their employees and for their customers concerning the MCA. The programs include a drug abuse prevention message relating to methamphetamine and an explanation of the firm's corresponding voluntary program to ensure their products do not contribute to the illicit manufacture of methamphetamine. Such programs include suggested notification for employees of retail distributors as to what products are restricted under the MCA, and what to do if a retail customer attempts to purchase more than the designated amount of a restricted OTC medication.

**3) List of OTC Products:** Several major wholesalers have reviewed the sales and trend data for OTC products they distribute and which may be diverted for the illicit manufacture of methamphetamine. As a result, they have produced a distribution list and forwarded a courtesy copy to DEA. Such information, in conjunction with law enforcement intelligence, will be very useful in identifying sources of those products used in the illicit manufacture of methamphetamine.

If the remainder of the chemical industry will undertake these and similar voluntary measures, a tremendous impact can be made on the availability of illicitly-produced controlled substances in the United States.

**Appendix E-1**

# Suspicious Orders Task Force

PubLaw 104-237 Title V, § 504, Oct 3, 1996
The entire report can be viewed on the Diversion Control internet site:
www.deadiversion.usdoj.gov
Choose "Publications," then "program reports"

The law, 21 U.S.C. § 830(b)(1)(A), requires that each regulated person shall report to the Attorney General any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. While the CSA requires reporting of suspicious orders, the manner in which industry addresses the requirement determines its effectiveness.

Representatives of government and the chemical industry worked together in 1998 in the Suspicious Orders Task Force to develop voluntary guidelines for recognizing suspicious orders. The Task Force guidelines, entitled "Suspicious Orders Identification Criteria," were endorsed by the Attorney General and widely accepted by industry. The criteria, which are for voluntary use, are specific for each segment of the chemical distribution industry: Importers & Manufacturers; Wholesale Distributors; and Retail Distributors. Task Force guidelines appear in the appendices.

The Task Force recommended that manufacturers of retail over-the-counter drug products containing List I chemicals utilize "ordinary over-the-counter" packaging as defined in the MCA and that products packaged differently be prepared and distributed only for prescription use as defined by the Food, Drug and Cosmetic Act. The industry has widely accepted this recommendation. Industry has distributed the guidelines and incorporated them into employee training programs.

### Suspicious Orders Identification Criteria

Each regulated entity is most familiar with its customers and circumstances surrounding the orders it processes. The chemical industry must use its best judgment in identifying suspicious orders. The following criteria are provided in order to assist the industry in identifying suspicious orders.